

02/26/01
combined with a stromal support matrix populated with actively growing stromal cells.

[(amended) The method of claim [1] 16, wherein [a] the stromal support matrix comprises fibroblasts.]

90. (amended) The method of claim 76, wherein the tissue substrate is selected from a group consisting of bladders, intestines, tubes, esophagus, ureters, arteries, veins, stomachs, lungs, hearts, colons, and skin[.].

REMARKS

Claims 15, 48, 49 and 90 have been amended above to overcome the rejection under 35 U.S.C. § 112.

Claims 1-24, 36-55, 74, and 76-99 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Gregory et al, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Gregory et al in view of Labroo et al.

Applicant has previously amended this application to provide that it is a continuation-in-part of U.S. Serial No. 08/341,881, filed November 15, 1994 ("USSN '881"), and a continuation-in-part of USSN 08/658,855 filed on May 31, 1996 ("USSN '855"). USSN '881 is the parent application of the Gregory et al reference cited by the Examiner. A Declaration of Prior Invention in the United States to Overcome a Cited Publication under 37 C.F.R. 1.131 has been previously presented to the Examiner. In that Declaration it is established that the invention of the pending claims was made at least by a date earlier than the effective date of the Gregory et al reference. The parties making the Declaration are Dr. Kenton Gregory and Mr. Andrew Barofsky, the co-inventors of the above referenced application. Dr. Gregory is also one of the co-inventors of the PCT publication which is in fact the Gregory et al reference. This Declaration overcomes the Gregory et al reference and renders moot all rejections based thereon. Accordingly, Gregory et al cannot be cited as a prior art reference against this application, particularly either under 35 U.S.C. § 102(a) or under 35 U.S.C. § 103(a).

Regarding Labroo et al, the shortcomings of that reference have been pointed out in detail in the prior responses of Applicants to that prior art reference.

In order to have anticipation under 35 USC Section 102 (b), every element of the claim must be found in the prior art reference. As stated above, Gregory et al is not a valid reference. Labroo et al does not contemplate, suggest or teach the use of tropoelastin except as a second component of a copolymer the different first peptide monomers disclosed therein. Therefore, the requirements for a *prima facie* case of anticipation have not been met by the Labroo reference with respect to the rejected claims.

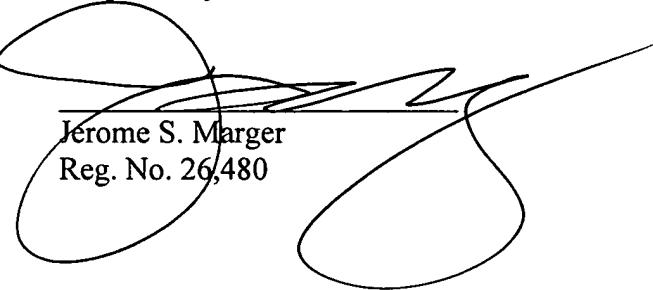
Claims 47 and 48 have been rejected under 35 U.S.C. § 102 (b) as being anticipated by Rabaud et al. In order to have anticipation under 35 USC Section 102 (b), as previously stated, every element of the claim must be found in the prior art reference. A Declaration under 37 C.F.R. 1.132 has been provided to the Examiner. The party making the Declaration is Dr. Kenton Gregory, one of the co-inventors of the above referenced application. Dr. Gregory is a cardiologist and the Director of the Oregon Medical Laser Center. The Gregory Declaration is provided to distinguish the teachings of the Rabaud et al patent (U.S. 5,223,420) from the pending claims of the present invention. Certain conclusions are clear from reading the Rabaud et al reference and the Gregory Declaration. First, Rabaud et al. does not relate to the use or production of an elastin or tropoelastin composition except wherein fibrin is a essential component of that composition. Second, fibrin is included in the composition disclosed in Rabaud et al. because Rabaud has determined that fibrin is necessary to crosslink or polymerize the elastin into a matrix. Third, the presence of fibrin in the composition disclosed in Rabaud et al. makes it thrombogenic. As stated by Rabaud, "it is not possible to use the material as artery substitute because of its natural thrombogeneity". See M. Rabaud et al., A New Biodegradable Elastin-Fibrin Material; Its Use in Urological, Digestive, and Cardiovascular Surgery, 7 J. Biomaterials Applications 20, 44 (1992). Unlike Rabaud et al., the invention described by the present application does not contain fibrin and, therefore, should make possible tissue prostheses

that are suitable for numerous in vivo uses. Therefore, the requirements for a prima facie case of anticipation have not been met by the Rabaud et al reference with respect to the rejected claims.

Claims 36 to 48 and 55 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Schwartz et al. In claims 36 to 48 and 55, applicant has added the language that the biomaterial employed is "consisting essentially of" tropoelastin. In order to have anticipation under 35 U.S.C. § 102(b), each and every element of the claim must be found in the prior art reference. Schwartz et al does not disclose, suggest or teach the use of tropoelastin. Schwartz et al discloses the use of the material described in the Rabaud et al reference cited above as a covering on a stent substrate. All of the discussion and arguments presented above with respect to the inapplicability of the Rabaud et al reference to the subject invention, apply as well to the Schwartz et al reference. Therefore, the requirements for a prima facie case of anticipation have not been met with respect to the rejection of claims 36 to 48 and 55 as being anticipated by the Schwartz et al reference.

In light of the above arguments and amendments to the claims, it is requested that the Examiner reconsider his rejections and pass this case to issue. If, however, the Examiner still believes that has not responded to all of the rejections presently outstanding, he is encouraged to call the Attorney for the Applicants at the telephone number below to discuss same.

Respectfully submitted,



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